Spectral MD™

5. 510(k) SUMMARY

K124049

APR 18 2013

Submitter:	Spectral MD™, Inc. 5959 Harry Hines Blvd. Professional Office Building 1, Suite 426 Dallas, Texas 75235
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Date Prepared:	December 28, 2012 *revised March 25, 2013*
Trade Name:	DeepView Digital Video Physiological Portable Imaging System
Common Name:	Extravascular Blood Flow Probe
Classification Name:	DPT 870.2120 Probe, Blood Flow, Extravascular DQA 870.2700 Oximeter
Predicate Device:	K980383 Moor Instruments - moorLDI Laser Doppler Imager K032841 Moor Instruments – moorLDI2-IR Infrared Laser Doppler Imager K023044 Nonin – Avant Model 9600 Pulse Oximeter
Device Description:	DeepView system–based technology combines real–time digital analysis of optical signatures, thereby sensitizing an imager to photon–tissue interactions deep below the skin's surface. These image signatures are unique to the body and relate directly to a person's dynamic nature – both in terms of the quantity and quality of important physiological properties. This technology is non–invasive and uses no harmful radiation such as X–rays and allows clinical investigators to look deeper into the body, delivering images of blood flow under the skin's surface without ever touching the patient. The DeepView system is composed of a mobile cart with uninterruptible power supply, a laptop computer with remote multimedia keyboard, an LCD screen mounted on a bracket that allows for side-to-side panning, a mechanical arm, a CMOS camera with DSP electronics, and disposable LED cartridges with an associated LED driver control board.
Statement of Intended Use:	The Spectral MD DeepView system is intended for studies of blood flow in the microcirculation. The DeepView system is suitable for a wide variety of clinical applications including plastic surgery, diabetes, dermatology, vascular surgery, wound healing, neurology, physiology, neurosurgery and anesthetics.

Summary of Technological Characteristics:	The *DeepView* uses infrared light to detect pulsatile blood flow in patients, and then provides 2D color images of relative perfusion distribution to healthcare providers. The technology used is non contact Photoplethysmography (PPG). PPG allows the *DeepView* to take advantage of the deep penetration of near IR light in human tissue. The *DeepView*, as well as all three predicate devices, is portable and use software to control the device operations, collect the patient data, analyze the data, present the data to the user, etc. The DeepView displays 2D color images demonstrating relative blood flow, similar to the moorLDI and moorLDI2-IR predicate devices. The new device and the three predicate devices can all store patient data, which can then be examined later by healthcare professionals. The *DeepView* and the moorLDI and moorLDI2-IR are non-contact regarding patient interaction. All devices (new and predicate) require light and optics for detection of blood flow. The two predicate imaging devices (moorLDI and moorLDI2-IR) use laser illumination, while the *DeepView* device and predicate Avant 9600 device use LED illumination.
Summary of Test Data:	Direct comparison testing was performed with both the moorLDI and Avant 9600 predicates. Comparison testing was conducted to demonstrate that the DeepView can, using optical methods, detect blood flow and pulse pressure. Using these attributes, DeepView was tested alongside the predicate devices to show substantial equivalence in detecting pulse frequency and in producing flow images. Comparison testing included camera distance testing and tissue phantom testing. The comparison testing conducted demonstrates that the *DeepView* is substantially equivalent to the predicate devices identified and does not introduce any new issues of safety and efficacy.
Conclusion:	*Spectral MD™, Inc.* considers the *DeepView* to be substantially equivalent to the predicate devices listed above This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 18, 2013

Spectral MD™, Inc.
% Ken Block Consulting
Ms. Diane Rutherford, BSME, MSMSE
1201 Richardson Drive, Suite 280
Richardson, Texas 75080

Re: K124049
Trade/Device Name: DeepView Digital Video Physiological Portable Imaging System
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular blood flow probe
Regulatory Class: Class II
Product Code: DPT
Dated: March 25, 2013
Received: March 28, 2013

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: **K124049**

Device Name: *DeepView*

Indications for Use:

The Spectral MD DeepView system is intended for studies of blood flow in the microcirculation. The DeepView system is suitable for a wide variety of clinical applications including plastic surgery, diabetes, dermatology, vascular surgery, wound healing, neurology, physiology, neurosurgery and anesthetics.

Prescription Use X___ AND/OR Over-the-Counter Use

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

Neil R Ogden -S
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(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number ___K124049_____